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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,818	06/26/2003	Thomas Nilsson	239637US0	2767

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,818	NILSSON ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 01/09/06. All claims are amended, no claims added and no claims cancelled. Accordingly claims 1-17 are pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-13, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin (WO 0178737) in view of Haikrainen et al (WO 0064519).

Gavin teaches medical combinations comprising **formoterol and budesonide**. The combinations are used for prophylaxis and treatment of respiratory diseases (see abstract). The active agents may be a racemate, solvate, hydrate or functional derivative thereof. The formulations may comprise other active agents such as fluticasone propionate, beclomethasone dipropionate, mometasone furoate or triamcinolone acetonide, sodium cromoglycate, nedocromil sodium, leukotriene antagonists, salbutamol, salmeterol, tiotropium, etc (see pages 5-6). The formulations may be in a form for inhalation such as **fine particle** dust administered via **metered dose aerosols**. Formulations for inhalation include **powder** compositions which will preferably contain lactose. The active ingredients will have a particle size of less than 100 microns, and preferably from 1 to 5 microns (see page 6).

The amounts of each active agent is disclosed in various examples, such as example 3, where a dry powder formulation comprises 24 microgram of (R,R)-formoterol fumarate and 200 microgram of budesonide, thus meeting the concentration limitation of claims such as claim 7. The process of making the said formulations are disclosed in page 9.

Gavin, discussed above, lacks specific disclosure on the separation of the powdered active ingredients on a common dose bed.

Haikrainen teaches powder inhaler for combined medicament. The device comprises **two or more medicament containers** for different **drug powders** which are inhaled as a combined medication, and separate aerosolization channels for **each drug** powder (see abstract and page 3). The inhaler of the present invention is able to deliver and **deaggregate** medicament powder from two or more dosing recesses simultaneously without the use of pressurized air (see page 2, lines 36-38). The first and the second medicament containers are separated so that the active ingredients can not be mixed during storage. The suitable combinations of active agents include **formoterol and budesonide**; salmeterol and beclomethasone dipropionate; salmeterol and fluticasone, etc (see page 4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have employed the method and device of Haikarainen et al to make and deliver particle formulations of two or more active agents as taught by Gavin because the method and device of Haikarainen is disclosed to be advantageous for

delivering powdered combination medicaments where by storing the active agents separately, the problem of aggregation is resolved.

Claims 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin (WO 0178737) in view of Haikrainen et al (WO 0064519) as applied to claims 1-4, 6-13, 15-17 above, and further in view of Trofast (6,030,604).

The combined references discussed above, while teaching a wide variety of bronchodilators and anti-inflammatory agents, lack specific disclosure on ciclesonide.

Trofast teaches a dry powder composition comprising one or more potent pharmaceutically active substances and a carrier substance, all of which are in finely divided form. The active substance suitable for use in the invention include **ciclesonide,** formoterol, budesonide, mometasone, fluticasone, salmeterol, etc (see col. 1, lines 26-62). The particle size of the active ingredients is said to be less than 10 microns and preferably between 1 and 7 microns. The formulations comprises about 6 microgram of formoterol and 100 microgram of budesonide per unit dose (see col. 2, lines 3-10 and 15-49). The said formulations can be administered via dry powder metered dose inhalers, to patients suffering form disorders such as respiratory disorders (col. 3, lines 20-31).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of the combined references, to have looked in the art for other and specific agents suitable for combination therapy such as ciclesonide, as taught by Trofast.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional double patenting rejections of claims 1-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/603,819 (20040258625), copending Application No. 10/870,907 (20050042174) and copending Application No. 10/870,909 (20050042175) are maintained.

Response to Arguments

Applicant's arguments with respect to claim01/09/06 have been considered but are moot in view of the new ground(s) of rejection. However Applicant's arguments relevant to combining references of Gavin and Haikrainen will be addressed.

Applicant argues that none of the references cited "would lead one of ordinary skill in the art to the presently claimed invention where a metered dry powder medicinal combined dose is prepared on a common dose bed". This is not persuasive. Although

neither Gavin nor Haikrainen specifically disclose a common dose bed they disclose a very similar method of delivering the two or more active agents separately and avoiding mixing them before administration. In Haikrainen's reference the medicaments are stored in a compartment compared to the dose bed of the instant invention. However, the end result is the same.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
March 31, 2006

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER